4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2149]

Jonathan Doyle: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jonathan Doyle for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Doyle was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Doyle was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of April 8, 2021 (30 days after receipt of the notice), Mr. Doyle has not responded. Mr. Doyle's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On October 15, 2020, Mr. Doyle was convicted as defined in section 306(*l*)(1)(A) of the FD&C Act , in the U.S. District Court for the Northern District of Texas-Dallas Division, when the court accepted Mr. Doyle's plea of guilty and entered judgment against him for the offense of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)).

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: as contained in the factual résumé, dated February 15, 2019, in Mr. Doyle's case, he was the President of USPlabs, LLC (USP Labs), and owned 45 percent of the company. USP Labs sold dietary supplements. Beginning in or around October 2008 and continuing until at least in or around August 2014, Mr. Doyle engaged in a conspiracy with others to import and ship in interstate commerce a variety of chemicals for use and prospective use in dietary supplements with false labeling. To further this conspiracy, Mr. Doyle's coconspirators ordered chemicals from Chinese chemical sellers to be used as ingredients in dietary supplements and had them labeled falsely as other food substances. USP Labs sold dietary supplements called Jack3d and OxyElite Pro, both of which originally contained a substance called 1,3-dimethylamylamine (DMAA), which is also known as methylhexaneamine. USP Labs imported numerous substances intended for human consumption, including DMAA, using false and fraudulent Certificates of Analysis (COA) and other false and fraudulent documentation and labeling. At least some of the false COAs that USP Labs caused to be created for their DMAA shipments stated falsely that the substance in the shipments had been

extracted from the geranium plant. Further, on or about December 8, 2011, Mr. Doyle's coconspirator instructed a Chinese chemical seller via email to misbrand a shipment of nine different chemicals sent from China to USP Labs in Texas. One of those synthetic chemicals was called "aegeline." The first aegeline-containing version of OxyElite Pro, which was called OxyElite "New Formula," went on sale in December 2012. In summer 2013, USP Labs reformulated the product again to contain aegeline and powder derived from a Chinese herb called cynanchum auriculatum. On or about June 15, 2013, Mr. Doyle's coconspirator instructed a Chinese chemical seller to have two metric tons of ground cynanchum auriculatum root powder shipped internationally to SK Laboratories in California for inclusion in USP Labs' products, using the false name "cynanchum auriculatum root extract." USP Labs sent false labels listing "cynanchum auriculatum (root) extract" as an ingredient in its OxyElite Pro "Advanced Formula" supplement, even though that ingredient was not present in the product. The conspirators collected millions in revenue that they would not have obtained, absent the conspiracy.

As a result of this conviction FDA sent Mr. Doyle, by certified mail on March 4, 2021, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Doyle's felony conviction of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 21 U.S.C. 333(a)(2)), constitutes conduct relating to the importation into the United States of an article of food because the offense involved a conspiracy to import a variety of chemicals with false labeling in order to either use those chemicals in dietary supplements which would themselves also contain false labeling or to determine whether those chemicals could be used in new dietary supplements.

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Doyle should be subject to a 5-

year period of debarment. The proposal also offered Mr. Doyle an opportunity to request a hearing, providing Mr. Doyle 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Doyle that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Doyle failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Jonathan Doyle has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Doyle is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].** Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Jonathan Doyle is a prohibited act.

Any application by Mr. Doyle for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2020-N-2149 and sent to the Dockets Management Staff (ADDRESSSES). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at https://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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